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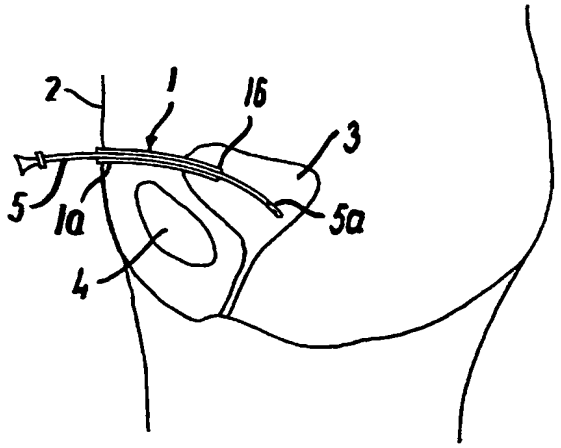
(54) Title: AN ACCESS MEMBER AND A SYSTEM FOR CATHETERIZATION OF THE URINARY BLADDER THROUGH AN ARTIFICIAL OR A NATURAL CANAL IN A USER, AND A METHOD OF REPLACING SUCH AN ACCESS MEMBER



(57) Abstract: In the system an access member (1) is provided, said access member having an outer end (1a) and an inner end (1b). The access member is adapted to extend from the outside of the body through the canal which may be an artificial canal extending from the user's abdominal wall (2) to the bladder (3) and into the bladder, and has at least one cavity extending substantially throughout the length of the access member. The walls of the access member are made from a flexible material.

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An access member and a system for catheterization of the urinary bladder through an artificial or a natural canal in a user, and a method of replacing such an access member.

BACKGROUND OF THE INVENTION.

The present invention relates to an access member and a system for catheterization of the urinary bladder through an artificial or a natural canal in a user. The invention furthermore relates to a method of replacing such an access member

Catheterization may typically be necessary in the case of postoperative urine retention of newly operated patients in a hospital. Another typical use is with patients suffering from severe cases of urinary incontinence as for disabled individuals like para- or tetraplegics who frequently have no control permitting voluntary urination.

Traditionally, such catheterization is carried out by inserting a catheter through the urethra of the patient. The catheter may be left in place for permanent catheterization during several hours or days, which is typically the case in elderly and infirm patients, or be retracted after emptying of the bladder, ie. so-called intermittent catheterization (IC).

Access to the urinary bladder may likewise be desirable in order to introduce eg. pharmaceuticals into the bladder or in order to wash or rinse the bladder.

Intermittent urethral catheterization performed with intervals of eg. 3 to 6 hours reduces the risk of infection of urethra and the bladder significantly as compared to permanent catheterization and has for many users become increasingly common also in daily life

situations outside the clinical environment of a hospital, whereby a significantly improved quality of life has been obtained for this group of patients.

However, intermittent catheterization requires a certain degree of dexterity and mobility which implies that self-catheterization is not always possible, especially in women where the urethral orifice may be difficult to locate.

During recent years, suprapubic catheterization (SPC) has been introduced as an alternative to urethral catheterization. In suprapubic catheterization, a canal is made from the surface skin of the abdominal wall of a user into the bladder under local or general anaesthetia and by means of a pointed hollow introducer or trocar. After penetration of the trocar into the bladder, a catheter is inserted through the canal thus provided, the inner end of said catheter being retained in the bladder by means of eg. an inflatable balloon abutting the inner wall of the bladder after retraction of the trocar. Although many of the disadvantages connected with urethral catheterization, such as eg. urethral cleavage and urethritis, may be overcome by this technique, infection risk is still high as suprapubic catheterization is typically performed as permanent catheterization due to the fact that the canal may close during replacement of the catheter. Furthermore, the fact that the end of the catheter protrudes well into the bladder when using a balloon, which is necessarily placed at a distance from the end in order to allow in-flow of urine, means that the bladder wall may be injured, the more so as the bladder wall often assumes an at least partially collapsed position in which it rests on the end of the catheter.

GB patent No. 2 275 420 discloses a system for suprapubic catheterization of the bladder permitting

intermittent catheterization by means of an accessor or sealing member permanently lodged in the artificial canal. The accessor comprises an outer shell formed by two elongate leaves of a bendable plastics material which are hinged together along one edge and having flanges at one end for securing the accessor to the skin surface. A sealing means in the form of a balloon assembly keeps the canal formed in the accessor closed between emptyings but allows insertion of the catheter. Due to the size and material of the accessor, this system may cause discomfort to the user.

Another alternative is provided by the so-called Mitrofanoff principle, by which a suprapubic canal is surgically made by removing parts of a body section, such as the appendix, another part of the intestinal system, eg. a section of the ileum, or any other suitable tubular body tissue, and subsequently attaching one end of the section to the abdominal skin surface whereas the other end penetrates the bladder wall and possibly protrudes into the bladder, the part being attached to the bladder wall at the point of penetration. Obviously, this technique requires surgery under general anaesthetia and implies a loss of bowel or other tissue as well as stitches in the bladder wall.

SUMMARY OF THE INVENTION.

It is an object of the present invention to provide an access member for use in catheterization of the urinary bladder, which is comfortable to wear and which at the same time provides for an appropriate security against leakage.

It is a further object to provide an access member, by which intermittent catheterization may be performed by a larger group of users and which

alleviates the problems encountered in the prior art.

These and other objects are met by an access member adapted to be, in a position of use, accommodated in an artificial or a natural canal in a user, said access member having an outer end and an inner end defining a predetermined length and extending, in the position of use, from the outside of the body of the user through said canal and into the urinary bladder, and comprising at least one wall defining at least one cavity extending substantially throughout said predetermined length, said at least one cavity being intended for intermittently receiving a catheter, said access member being characterized in that said at least one wall of the access member is flexible, such that said at least one cavity is kept in a substantially closed position but allows for intermittent insertion of a catheter.

The flexibility of the wall or walls of the access member entail that the access member itself is able to provide for the necessary sealing properties, as the access member will inherently have the effect of an automatic non-return valve. In case the access member is exposed to forces in the radial or longitudinal directions, the wall of the access member is pressed against itself or, alternatively, the walls are pressed against each other, thus closing the through-going cavity of the access member between catheterizations, either by a collapse in the radial direction and/or by a bend at the entrance into the bladder. At the inner end of the access member, the cavity is kept closed eg. by contraction of the detrusor and possibly by the pressure exerted by the urine collected in the bladder. By integrating the sealing properties in the access member, it is possible to make the access member according to the invention

very comfortable to wear.

During use in connection with suprapubic catheterization, in which the body canal is an artificial canal extending from the user's abdominal wall, contraction of the abdominal muscles keeps the part of the through-going cavity of the access member, which is situated in the region of the abdominal wall, closed, so that urine may not penetrate to the outside and consequently that eg. water may not seep into the bladder when the user is washing or bathing. Nevertheless, intermittent catheterization may be carried out without difficulty by inserting the catheter through the passage provided by the cavity or cavities of the access member.

In relation to the Mitrofanoff principle, the access member according to the invention does not necessarily require surgery under general anaesthetia or any loss of body tissue. By this design an access member is provided which makes intermittent catheterization a feasible and/or attractive alternative to a large number of users which hitherto have been forced to use permanent catheterization. As a consequence, it is possible to reduce the risk of infection in this group of users.

The wall or walls of the access member may comprise a foil or film material, or a foam or a gel. It is likewise possible to form at least a part of the wall or walls of the access member of a net material of eg. metal.

The access member may comprise one wall forming a substantially hose-shaped access member, which provides for a simple manufacture of the access member. The access member may eg. be produced by extrusion or by any other method which provides a preferably seam-less access member.

Alternatively, the access member may comprise at least two walls which are formed by sheets of material having substantially larger dimensions in the longitudinal direction than in the transverse direction and being joined at the respective longitudinally extending edges. By this design, a particularly effective sealing is provided. The sheets may eg. be joined by means of welding, adhesion or any other suitable joining technique.

In order to control the insertion of the access member properly, said sheets may have different thicknesses and different degrees of flexibility. Hereby, it is possible to control the rigidity in the axial direction of the access member.

In an embodiment, which is particularly advantageous with respect to the insertion, at least one blind hole is provided in at least one of said sheets.

In a further embodiment, in which there are at least three sheets and two cavities, and which is particularly advantageous with respect to the insertion as well, one of said cavities is closed at a distance from the outer end of the access member.

In both of these latter embodiments, a suitable fluid, eg. air, may be introduced into the blind hole alternatively the closed cavity, thus increasing the rigidity of the access member in the longitudinal direction thereof during insertion of a catheter whereby the insertion is facilitated.

In an embodiment, which is relatively simple to manufacture and which provides for an easy insertion, the inner end of the access member is designed as a cap having a number of openings.

The access member may furthermore comprise means for securing the outer end of the access member to the

abdominal skin surface. Said means may eg. comprise a plate-shaped member, which may be fastened to the skin surface by means of sewing or by adhesion.

In order to provide for additional security against leakage into the access member from the outside, a plug may be provided for introduction into the outer end of said at least one through-going cavity.

In another aspect of the invention, a system for catheterization is provided.

In yet another aspect, a method of replacing an access member is provided. Replacement of the access member may take place by removing the existing access member and shortly after inserting the new access member. If necessary, the new access member may be introduced through the existing one while still in place, whereafter the old one is removed.

BRIEF DESCRIPTION OF THE DRAWINGS.

In the following the invention will be described in detail with reference to the schematic drawings, in which

Fig. 1 shows a side view of a system according to the invention during catheterization;

Fig. 2 shows a side view of an access member according to the invention in a position of use;

Fig. 3 shows, at a larger scale, a part sectional view of a detail of a system according to another embodiment of the invention;

Figs. 4 to 8 show, at a larger scale and very schematic, cross-sectional views of different embodiments of an access member according to the invention; and

Fig. 9 shows a view corresponding to Fig. 2 of a further embodiment of an access member according to the

invention.

DETAILED DESCRIPTION OF THE INVENTION.

In Figs. 1 and 2 a system for suprapubic catheterization is shown, in which an access member 1 is shown in its position of use in a canal extending from the skin surface 2 of the abdominal wall of the user, which in this case is a female, to the urinary bladder 3, said canal extending above the pubic bone 4. The access member 1 is essentially formed as a hollow tube made from a suitable flexible material. The term "tube" should be interpreted in its broadest sense, ie. as comprising any element having at least one longitudinally extending cavity.

The wall or walls of the access member is/are formed with a small thickness, which in this respect means that the thickness should be sufficiently low so as to be able to allow parts of one wall, or different walls to contact each other. A preferred thickness depends on the material chosen.

Examples of suitable materials are eg. film or foil made from polyethylene, polyurethane, polypropylene or like material, a flexible foam made from any suitable material, artificial blood vessels, pig guts, Tripsin, a gel, such as a hydrogel or a silicone gel which are widely used for eg. implants or any other gel, or any other material which can meet the demands to the access member, both with respect to physical properties and bio-compatibility. In addition to being flexible and being able to be produced in a small thickness, the material should thus preferably be soft, possess low surface friction, be able to be coated, welded, heat-sealed and/or glued, adhered or joined using any other suitable joining technique and be hydrophobic. Furthermore, the material should be able

to collapse in a radial direction but preferably be stable axially, and could for insertion purposes be rolled up. With respect to the bio-compatibility of the material, it should prevent stenosis, encrustation and bio-film formation, not form in-growth with tissue and be non-toxic.

Parts of the access member may comprise different materials. For instance, the part situated in the region of the abdominal wall could be designed of a net material of eg. metal.

In order to prevent or reduce even further these unwanted effects, the access member may be provided with a coating on the outer side and/or the inner side. The coating may eg. contain antibacterial agents or disinfectants known per se, such as metal ions, halogen ions, antibiotics or sulpha. It is also possible that the wall or walls of the access member may have properties allowing slow release of any known antibacterial or disinfective substances.

The access member 1 has an outer end 1a which may be secured to the skin surface 2 by any suitable means, eg. a medical grade adhesive, and an inner end 1b which protrudes well into the bladder 3, the outer and inner ends 1a,1b defining a predetermined length. Examples of suitable adhesives are adhesives based on styrene-isoprene-styrene block polymer (SIS), polyisobutylene (PIB), Silicone Tacky Gel, polyvinylether (PVE) and acrylic polymers. In the embodiment shown, the cavity in the access member 1 extends throughout the predetermined length such that a catheter 5 may be inserted through the canal provided by the access member 1 in order to attain the catheterization position as shown in Fig. 1, in which urine flows from the bladder 3 through inlet openings 5a provided at the end of the catheter and out to a suitable draining

means (not shown).

After catheterization, the catheter 5 is retracted from the bladder 3 through the access member 1 which remains seated in the body of the user.

As indicated in Fig. 2 the access member 1 assumes, at least partially, a flattened position between catheterizations as a result of the involuntary contraction of the detrusor and abdominal muscles, and of the pressure exerted by the urine collected in the bladder, respectively. Consequently, the passage between the bladder 3 and the outside of the body provided by the cavity in the access member is kept closed such that virtually no urine may penetrate to the outside. Moreover, the closure of the canal implies that liquid such as water will not seep into the bladder when the user for example washes, takes a shower or bathes.

Initial positioning of the access member 1 may take place by first penetrating the abdominal wall and the wall of the bladder 3 by means of a trocar and by subsequently inserting a catheter or other applicator means carrying on its outer or inner side the access member 1.

In order to insert the access member 1 without discomfort to the user, the exterior surface of the access member may be provided with a coating to provide a slippery low-friction surface character. In order to retain the access member safely within the body the coating may be of a temporary character such that the exterior surface after a predetermined period of time looses its low-friction character.

Alternatively, application of the access member may take place as shown in Fig. 3, showing a part of an embodiment of the inventive system comprising a catheter 25 and an access member 21. In this

embodiment, an inner end 21b of the access member 21 adapted to be positioned at the end of the catheter 25 provided with urine inlet openings 25a is designed as a cap having openings 21c which allow urine to flow into the catheter 25 through the inlet openings 25a.

In the following, different designs of the access member will be described with reference to Figs. 4 to 8. In these very schematic cross-sectional views, certain details of the access member may be omitted, ie. the access member may comprise parts not indicated in theses Figures.

In its most simplified form as shown in Fig. 4, the access member 41 comprises only one circumferential wall 42 which defines a cavity 45 for receiving a catheter during catheterization, thus providing the access member 41 with a substantially hose-shaped appearance. It should be noted that the access member 41 is shown in an open or catheter-receiving position, and it is to be understood that the cavity 45 is kept closed between catheterizations as parts of the wall 42 are pressed against each other.

In the Fig. 5 embodiment, the access member 51 comprises two walls which are formed by sheets 52,53 of material having substantially larger dimensions in the longitudinal direction than in the transverse direction and being joined at the respective longitudinally extending edges. The cavity 55 defined by the sheets 52,53 is shown in a slightly open position for reasons of clarity only. In one sheet 53, a blind hole 54 is provided in any suitable manner. During insertion of the access member 51 into the canal, a suitable fluid, eg. air, is introduced into the blind hole 54. As long as the fluid is present in the hole 54, the rigidity of the access member in the longitudinal direction thereof is increased, and the insertion of the access member 51

into the canal is eased.

A similar principle is shown in Fig. 6, in which the access member 61 comprises three walls likewise formed by sheets 62,63,64 of any suitable material, of which sheets 62 and 63 define the catheter receiving cavity 65. The cavity 66 defined between sheets 64 and 63 is closed at a distance from the outer end of the access member, and eg. air may be introduced into the closed cavity 66 in order to ease insertion of the access member 61.

In the Fig. 7 embodiment, the sheets 72,73 forming the walls of the access member 71 have different thicknesses and may in addition thereto have different degrees of flexibility. In this manner secure closing of the cavity as well as an eased introduction is ensured. In addition or alternatively, the thickness and/or the degree of flexibility may vary in the circumferential direction of the access member.

In the embodiment shown in Fig. 8 the cavity 85 defined by the sheets 82,83 forming the walls of the access member 81 is filled with a gel 86, which functions partly as a lubricant during insertion of the catheter, partly as an additional security against leakage.

In Fig. 9 an access member 91 which may be of any of the types described in the above is at its outer end 91a fastened to a plate-shaped member 93, eg. by means of a layer of adhesive 92 or in any other way, such as eg. by forming the plate-shaped member 93 integrally with the access member 91. The plate-shaped member 93 is in turn fastened to the abdominal skin surface by means of eg. a layer 94 of medical grade adhesive. A plug member 95 which is intended to be inserted into the outer end 91a of the access member 91 provides for increased safety against in-seeping of eg. water into

the access member 91. The plug member 95 may be coated as described in the above in connection with the coating of the access member itself.

The access member and the system according to the invention may alternatively be used in urethral catheterization. By using an access member in connection with urethral catheterization, self-catheterization may be performed even by users having a reduced dexterity and mobility as an access member facilitates the operation of finding the urethral orifice, especially in women. In contrast to permanent catheterization the muscles are furthermore allowed to contract and relax. By letting the outer end protrude from the urethral orifice, this end may easily be gripped by the user in order to position the catheter correctly. This operation is thus much facilitated in relation to urethral catheterization without an access member and makes it possible for even eg. sclerosis patients to perform intermittent self-catheterization which in turn implies that this group of patients gains a significantly improved quality of life in relation to use of permanent catheterization.

The access member or system may likewise be used for introduction of eg. pharmaceuticals into the urinary bladder or for washing/rinsing the bladder.

The invention is not limited to the embodiments shown and described in the above. Several modifications and combinations of the embodiments shown and described are conceivable within the scope of the appended claims.

C L A I M S

1. An access member adapted to be, in a position of use, accommodated in an artificial or a natural canal in a user, said access member having an outer end and an inner end and extending, in the position of use, from the outside of the body of the user through said canal and into the urinary bladder, and comprising at least one wall defining at least one cavity extending substantially throughout said predetermined length, said at least one cavity being intended for intermittently receiving a catheter, characterized in that said at least one wall of the access member is flexible, such that said at least one cavity is kept in a substantially closed position but allows for intermittent insertion of a catheter.

2. An access member according to claim 1, characterized in that the wall or walls of the access member comprise(s) a foil or film material.

3. An access member according to claim 1, characterized in that the wall or walls of the access member comprise(s) a foam or a gel.

4. An access member according to any of claims 1 to 3, characterized in that at least one part of the wall or walls of the access member comprises a net material of eg. metal.

5. An access member according to any of claims 1 to 4, characterized by comprising one wall forming a substantially hose-shaped access member.

6. An access member according to any of claims 1 to 4, characterized by comprising at least two walls which are formed by sheets of material having substantially larger dimensions in the longitudinal direction than in the transverse direction and being joined at the respective longitudinally extending

edges.

7. An access member according to claim 6, c h a r a c t e r i z e d in that said sheets are joined by means of welding, adhesion or any other suitable joining technique.

8. An access member according to claim 6 or 7, c h a r a c t e r i z e d in that said sheets have different thicknesses.

9. An access member according to any of claims 6 to 8, c h a r a c t e r i z e d in that said sheets have different degrees of flexibility.

10. An access member according to any of claims 6 to 9, c h a r a c t e r i z e d in that at least one blind hole is provided in at least one of said sheets.

11. An access member according to any of claims 6 to 9, in which there are at least three sheets and two cavities, c h a r a c t e r i z e d in that one of said cavities is closed at a distance from the outer end of the access member.

12. An access member according to any of the preceding claims, c h a r a c t e r i z e d in that the inner end of the access member is designed as a cap having a number of openings.

13. An access member according to any of the preceding claims, c h a r a c t e r i z e d by comprising means for securing the outer end of the access member to the abdominal skin surface.

14. An access member according to claim 13, c h a r a c t e r i z e d in that said means comprises a plate-shaped member.

15. An access member according to claim 13, c h a r a c t e r i z e d in that the plate-shaped member is fastened to the skin surface by means of an adhesive.

16. An access member according to any of the

preceding claims, c h a r a c t e r i z e d in that a plug member is provided for insertion into the outer end of said at least one through-going cavity.

17. A system for catheterization of the urinary bladder through an artificial or a natural canal in a user, comprising a catheter adapted to be inserted through the canal, and an access member according to any of claims 1 to 16.

18. A method of replacing an access member according to claim 1, in which a first access member positioned in said canal is removed and a second, substitute access member is inserted shortly afterwards, or a second, substitute access member is introduced through the first access member positioned in said canal whereafter the first access member is removed.

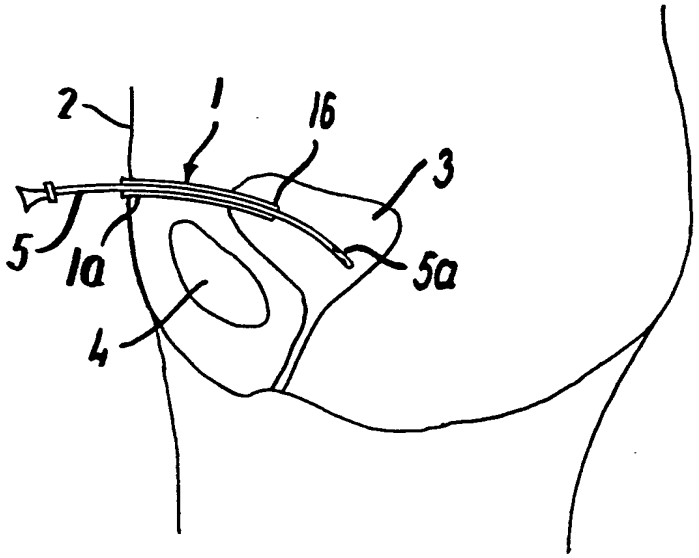

FIG.1

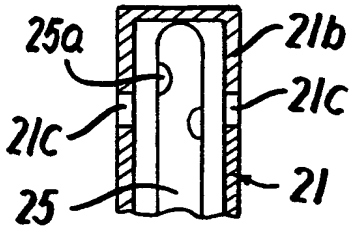

FIG.3

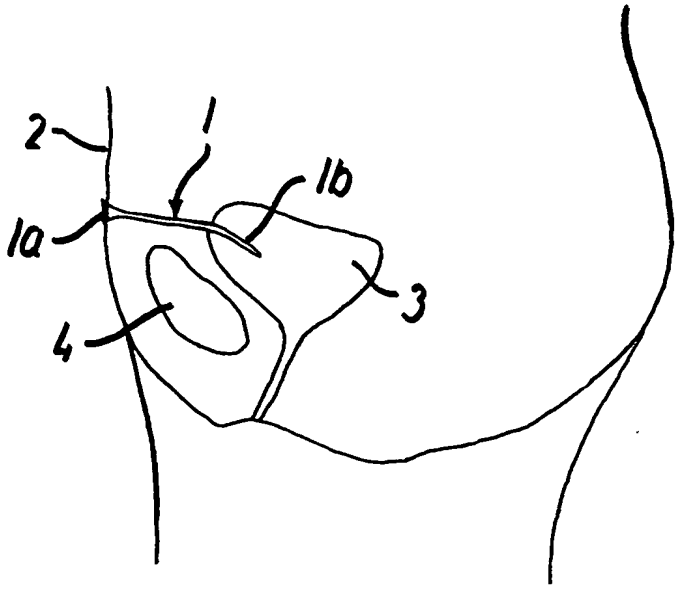

FIG.2

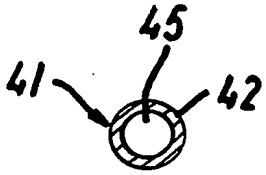

FIG. 4

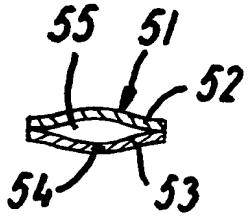

FIG. 5

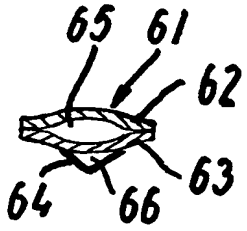

FIG. 6

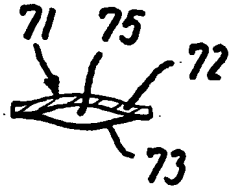

FIG. 7

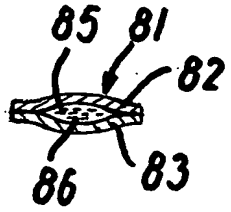

FIG. 8

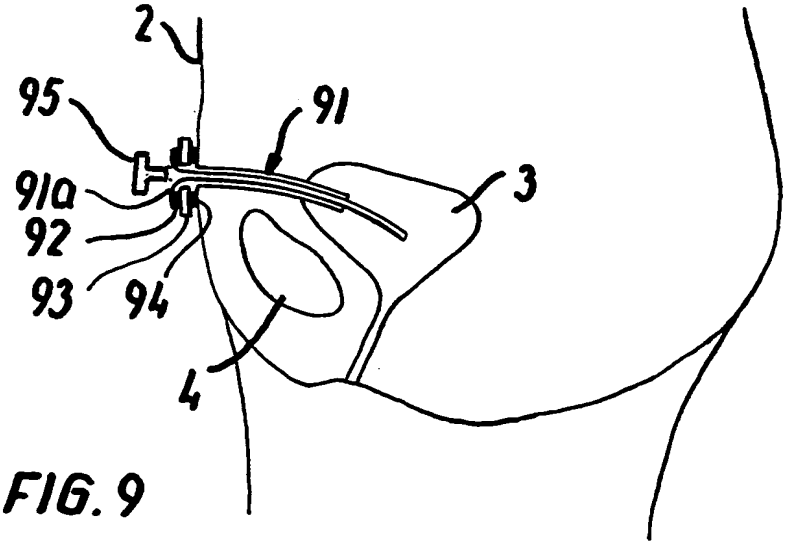

FIG. 9

INTERNATIONAL SEARCH REPORT

Inte ional Application No
PCT/DK 00/00361

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M25/01 A61M25/00 A61F2/00 A61B17/22

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GB 2 275 420 A (GAUNT DAVID RAMON ;GLICKMAN SCOTT (GB)) 31 August 1994 (1994-08-31) cited in the application page 16, line 6 - line 19; figures	1,2, 13-15,17
X	US 5 704 353 A (RAM MICHAEL J ET AL) 6 January 1998 (1998-01-06) column 3, line 8 -column 4, line 24; figures	1,13
X	US 5 417 666 A (COULTER PRINCE J) 23 May 1995 (1995-05-23) column 4, line 28 -column 5, line 48; figures	1,2,5,17

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
24 October 2000	02/11/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Kousouretas, I

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Inte onal Application No
PCT/DK 00/00361

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 684 369 A (WILDEMEERSCH DIRK A A) 4 August 1987 (1987-08-04) column 5, line 53 -column 6, line 29; figures	1,2,5,6, 17
A	US 5 806 527 A (BORODULIN GERMAN ET AL) 15 September 1998 (1998-09-15) abstract; figures	1,13
A	US 4 652 259 A (O'NEIL ALEXANDER G B) 24 March 1987 (1987-03-24) column 5, line 1 - line 57; figures	1

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int. Ional Application No
PCT/DK 00/00361

Patent document cited in search report		Publication date	Patent family member(s)			Publication date
GB 2275420	A	31-08-1994	NONE			
US 5704353	A	06-01-1998	US	5476434	A	19-12-1995
			US	5352182	A	04-10-1994
			AU	3320695	A	04-03-1996
			CA	2195949	A	15-02-1996
			CN	1159155	A	10-09-1997
			EP	0793465	A	10-09-1997
			JP	10507652	T	28-07-1998
			WO	9603942	A	15-02-1996
			US	5509889	A	23-04-1996
			AU	679185	B	26-06-1997
			AU	4522893	A	30-12-1993
			CA	2136318	A	09-12-1993
			DE	69316615	D	26-02-1998
			DE	69316615	T	20-08-1998
			EP	0642325	A	15-03-1995
			JP	8500982	T	06-02-1996
			RU	2107477	C	27-03-1998
			WO	9324075	A	09-12-1993
US 5417666	A	23-05-1995	NONE			
US 4684369	A	04-08-1987	BE	892838	A	02-08-1982
			BE	893679	A	18-10-1982
			AT	19953	T	15-06-1986
			DE	3363716	D	03-07-1986
			EP	0091895	A	19-10-1983
			JP	1690774	C	27-08-1992
			JP	3052988	B	13-08-1991
			JP	59011870	A	21-01-1984
US 5806527	A	15-09-1998	NONE			
US 4652259	A	24-03-1987	NONE			

NK

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION** see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
IPB/27127		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/DK 00/ 00361	03/07/2000	02/07/1999
Applicant		
COLOPLAST A/S		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 4 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language,** the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   [ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

   [ ] contained in the international application in written form.

   [ ] filed together with the international application in computer readable form.

   [ ] furnished subsequently to this Authority in written form.

   [ ] furnished subsequently to this Authority in computer readble form.

   [ ] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   [ ] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [X] **Certain claims were found unsearchable** (See Box I).

3. [ ] **Unity of invention is lacking** (see Box II).

4. With regard to the **title,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established, according to Rule 38.2(b). by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 1

   [X] as suggested by the applicant.

   [ ] because the applicant failed to suggest a figure.

   [ ] because this figure better characterizes the invention

   [ ] None of the figures.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
IPB/27127		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/DK00/00361	03/07/2000	02/07/1999
International Patent Classification (IPC) or national classification and IPC A61M25/01		
Applicant COLOPLAST A/S		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 6 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
24/11/2000	24.10.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer KÖRBER, C. Telephone No. +49 89 2399 2278

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/DK00/00361

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

1,2,5-13	as originally filed			
3,4,4a	as received on	20/09/2001	with letter of	18/09/2001

Claims, No.:

1-18	as received on	20/09/2001	with letter of	18/09/2001

Drawings, sheets:

1/2,2/2	as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   - ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   - ☐ the language of publication of the international application (under Rule 48.3(b)).
   - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   - ☐ contained in the international application in written form.
   - ☐ filed together with the international application in computer readable form.
   - ☐ furnished subsequently to this Authority in written form.
   - ☐ furnished subsequently to this Authority in computer readable form.
   - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application.

   ☒ claims Nos. 18.

because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

   ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☒ no international search report has been established for the said claims Nos. 18.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the standard.

   ☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1-3,5,13-15,17
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-17
Industrial applicability (IA)	Yes:	Claims	1-17
	No:	Claims	

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents cited in the ISR:

   D1: GB-A-2 275 420
   D2: US-A-5 704 353
   D3: US-A-5 417 666.

2.1 The subject-matter of claim 1 is known from document D1 as to be seen from the attached copy of the claim where the respective reference numerals and passages from D1 have been inserted.

2.2 The features of claim 1 are also anticipated by document D3 (see Figs. 1-4, with the flexible funnel member 4, see col. 3, l. 40-41 corresponding to the access member defined in claim 1; it is also considered that the length of this funnel member is as defined in claim 1, i.e. extending from the outside of the body of the user through some kind of an "artificial or natural canal" into the urinary bladder; in this respect it should be noted that anatomical dimensions may also vary widely depending on species, sex, age, etc.).

2.3 Accordingly, the subject-matter of claim 1 is not new (Article 33(2) PCT).

3. Dependent claims 2-16 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT), the reasons being as follows:

3.1 The features of claims 2, 3, 5, 13-15 and 17 are also known from D1 (p. 10, 2nd paragraph; Figs. 3 and 10).

3.2 Nothing inventive can be recognized in the additional features of claims 4,6-12 and 16.

Re Item VII
Certain defects in the international application

1. The independent claim is not properly delimitated against the prior art in accordance with Rule 6.3(b) PCT.

2. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

3. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D3 is not mentioned in the description, nor are these documents identified therein.

Re Item VIII
Certain observations on the international application

1. The term "any other suitable technique" used in claim 7 is vague and unclear and leaves the reader in doubt as to the meaning of the technical features to which it refer, thereby rendering the definition of the subject-matter of said claims unclear (Article 6 PCT).

2. The features in the apparatus claim 15 relate to a method of using the apparatus rather than clearly defining the apparatus in terms of its technical features. The intended limitations are therefore not clear from this claim, contrary to the requirements of Article 6 PCT.

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JC13 Rec'd PCT/PTO 31 DEC 2001

intermittent catheterization by means of an accessor or sealing member permanently lodged in the artificial canal. The accessor comprises an outer shell formed by two elongate leaves of a bendable plastics material which are hinged together along one edge and having flanges at one end for securing the accessor to the skin surface. A sealing means in the form of a balloon assembly keeps the canal formed in the accessor closed between emptyings but allows insertion of the catheter. Due to the size and material of the accessor, this system may cause discomfort to the user.

Another alternative is provided by the so-called Mitrofanoff principle, by which a suprapubic canal is surgically made by removing parts of a body section, such as the appendix, another part of the intestinal system, eg. a section of the ileum, or any other suitable tubular body tissue, and subsequently attaching one end of the section to the abdominal skin surface whereas the other end penetrates the bladder wall and possibly protrudes into the bladder, the part being attached to the bladder wall at the point of penetration. Obviously, this technique requires surgery under general anaesthetia and implies a loss of bowel or other tissue as well as stitches in the bladder wall.

US 5,704,353 discloses a catheter for temporary placement in the female urethra. The catheter comprises a shaft which in one end has a sealing portion and in the other end a cap. In the lumen of the shaft a one-way valve is enclosed, urine being drained upon activation of the valve by means of a spike. As the length of the shaft has to be adapted to the individual length of the user's urethra and due to the rather elaborate design, this device is expensive and complicated in manufacture. Furthermore, the presence

of the sealing portion, which is designed as a mushroom-shaped crown and which in the position of use rests against the inner surface of the bladder, may cause discomfort to the user.

SUMMARY OF THE INVENTION.

It is an object of the present invention to provide an access member for use in catheterization of the urinary bladder, which is comfortable to wear and which at the same time provides for an appropriate security against leakage.

It is a further object to provide an access member, by which intermittent catheterization may be performed by a larger group of users and which alleviates the problems encountered in the prior art.

These and other objects are met by an access member adapted to be, in a position of use, accommodated in an artificial or a natural canal in a user, said access member having an outer end and an inner end defining a predetermined length and extending, in the position of use, from the outside of the body of the user through said canal and into the urinary bladder, and comprising at least one wall defining at least one cavity extending substantially throughout said predetermined length, said at least one cavity being intended for intermittently receiving a catheter, said access member being characterized in that said at least one wall of the access member has such a degree of flexibility that said at least one cavity is kept in a substantially closed position by the mutual contact of parts of said at least one wall, but allows for intermittent insertion of a catheter.

The flexibility of the wall or walls of the access member entail that the access member itself is able to provide for the necessary sealing properties,

as the access member will inherently have the effect of an automatic non-return valve. In case the access member is exposed to forces in the radial or longitudinal directions, the wall of the access member is pressed against itself or, alternatively, the walls are pressed against each other, thus closing the through-going cavity of the access member between catheterizations, either by a collapse in the radial direction and/or by a bend at the entrance into the bladder. At the inner end of the access member, the cavity is kept closed eg. by contraction of the detrusor and possibly by the pressure exerted by the urine collected in the bladder. By integrating the sealing properties in the access member, it is possible to make the access member according to the invention

C L A I M S

1. An access member adapted to be, in a position of use, accommodated in an artificial or a natural canal in a user, said access member having an outer end and an inner end and extending, in the position of use, from the outside of the body of the user through said canal and into the urinary bladder, and comprising at least one wall defining at least one cavity extending substantially throughout said predetermined length, said at least one cavity being intended for intermittently receiving a catheter, c h a r a c t e r i z e d in that said at least one wall of the access member has such a degree of flexibility that said at least one cavity is kept in a substantially closed position by the mutual contact of parts of said at least one wall, but allows for intermittent insertion of a catheter.

2. An access member according to claim 1, c h a r a c t e r i z e d in that the wall or walls of the access member comprise(s) a foil or film material.

3. An access member according to claim 1, c h a r a c t e r i z e d in that the wall or walls of the access member comprise(s) a foam or a gel.

4. An access member according to any of claims 1 to 3, c h a r a c t e r i z e d in that at least one part of the wall or walls of the access member comprises a net material of eg. metal.

5. An access member according to any of claims 1 to 4, c h a r a c t e r i z e d by comprising one wall forming a substantially hose-shaped access member.

6. An access member according to any of claims 1 to 4, c h a r a c t e r i z e d by comprising at least two walls which are formed by sheets of material having substantially larger dimensions in the longitudinal direction than in the transverse direction and being

joined at the respective longitudinally extending edges.

7. An access member according to claim 6, c h a r a c t e r i z e d in that said sheets are joined by means of welding, adhesion or any other suitable joining technique.

8. An access member according to claim 6 or 7, c h a r a c t e r i z e d in that said sheets have different thicknesses.

9. An access member according to any of claims 6 to 8, c h a r a c t e r i z e d in that said sheets have different degrees of flexibility.

10. An access member according to any of claims 6 to 9, c h a r a c t e r i z e d in that at least one blind hole is provided in at least one of said sheets.

11. An access member according to any of claims 6 to 9, in which there are at least three sheets and two cavities, c h a r a c t e r i z e d in that one of said cavities is closed at a distance from the outer end of the access member.

12. An access member according to any of the preceding claims, c h a r a c t e r i z e d in that the inner end of the access member is designed as a cap having a number of openings.

13. An access member according to any of the preceding claims, c h a r a c t e r i z e d by comprising means for securing the outer end of the access member to the abdominal skin surface.

14. An access member according to claim 13, c h a r a c t e r i z e d in that said means comprises a plate-shaped member.

15. An access member according to claim 13, c h a r a c t e r i z e d in that the plate-shaped member is fastened to the skin surface by means of an adhesive.

16. An access member according to any of the preceding claims, c h a r a c t e r i z e d in that a plug member is provided for insertion into the outer end of said at least one through-going cavity.

17. A system for catheterization of the urinary bladder through an artificial or a natural canal in a user, comprising a catheter adapted to be inserted through the canal, and an access member according to any of claims 1 to 16.

18. A method of replacing an access member according to claim 1, in which a first access member positioned in said canal is removed and a second, substitute access member is inserted shortly afterwards, or a second, substitute access member is introduced through the first access member positioned in said canal whereafter the first access member is removed.

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Encl.

features known from D1

C L A I M S

1. An access member (2) adapted to be, in a position of use, accommodated in an artificial or a natural canal in a user, said access member having an outer end and an inner end and extending, in the position of use, from the outside of the body of the user through said canal and into the urinary bladder, (Fig. 3) and comprising at least one wall (28, 30) defining at least one cavity (Fig. 2) extending substantially throughout said predetermined length, said at least one cavity being intended for intermittently receiving a catheter, (6) characterized in that said at least one wall (28, 30) of the access member has such a degree of flexibility (p. 7, l. 3) that said at least one cavity is kept in a substantially closed position by the mutual contact of parts of said at least one wall (Fig. 3+4) but allows for intermittent insertion of a catheter. (p. 14, l. 3-7)

2. An access member according to claim 1, characterized in that the wall or walls of the access member comprise(s) a foil or film material.

3. An access member according to claim 1, characterized in that the wall or walls of the access member comprise(s) a foam or a gel.

4. An access member according to any of claims 1 to 3, characterized in that at least one part of the wall or walls of the access member comprises a net material of eg. metal.

5. An access member according to any of claims 1 to 4, characterized by comprising one wall forming a substantially hose-shaped access member.

6. An access member according to any of claims 1 to 4, characterized by comprising at least two walls which are formed by sheets of material having substantially larger dimensions in the longitudinal direction than in the transverse direction and being

PATENT COOPERATION TREATY

24 AUG 2000

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION CONCERNING SUBMISSION OR TRANSMITTAL OF PRIORITY DOCUMENT

(PCT Administrative Instructions, Section 411)

To:

CARLSSON, Eva
Internationalt Patent-Bureau
Høje Taastrup Boulevard 23
DK-2630 Taastrup
DANEMARK

Date of mailing (day/month/year) 18 August 2000 (18.08.00)	
Applicant's or agent's file reference IPB/27127	**IMPORTANT NOTIFICATION**
International application No. PCT/DK00/00361	International filing date (day/month/year) 03 July 2000 (03.07.00)
International publication date (day/month/year) Not yet published	Priority date (day/month/year) 02 July 1999 (02.07.99)
Applicant COLOPLAST A/S et al	

1. The applicant is hereby notified of the date of receipt (except where the letters "NR" appear in the right-hand column) by the International Bureau of the priority document(s) relating to the earlier application(s) indicated below. Unless otherwise indicated by an asterisk appearing next to a date of receipt, or by the letters "NR", in the right-hand column, the priority document concerned was submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b).

2. This updates and replaces any previously issued notification concerning submission or transmittal of priority documents.

3. An **asterisk(*)** appearing next to a date of receipt, in the right-hand column, denotes a priority document submitted or transmitted to the International Bureau but not in compliance with Rule 17.1(a) or (b). In such a case, **the attention of the applicant is directed** to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

4. The **letters "NR"** appearing in the right-hand column denote a priority document which was not received by the International Bureau or which the applicant did not request the receiving Office to prepare and transmit to the International Bureau, as provided by Rule 17.1(a) or (b), respectively. In such a case, **the attention of the applicant is directed** to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

Priority date	Priority application No.	Country or regional Office or PCT receiving Office	Date of receipt of priority document
02 July 1999 (02.07.99)	PA 1999 00958	DK	24 July 2000 (24.07.00)

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. (41-22) 740.14.35

Authorized officer

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Telephone No. (41-22) 338.83.38